

fibrosis.

Claim 30. A method for treating a liver disease in a patient comprising administering to the patient an effective amount of the isolated peptide of claim 21 or a composition comprising the isolated peptide of claim 21.

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Cont
Claim 31. The method according to claim 30, wherein the liver disease is hepatic fibrosis.

REMARKS

Claims 1-15 have been canceled in favor of new claims 16-31. Claim 16 corresponds to original claim 1, but has been rewritten to make clear that the structural similarity of the claimed peptide is tied to its antagonist activity. In addition, the number of amino acids in the peptides has been recited as between 9 and 23 in accordance with the Examples described, for example, on page 36 of the specification. The other new claims contain recitations that correspond to recitations in other of the claims as originally filed.

In response to the Official Action of September 18, 2002, wherein the Examiner has required an election between inventions, Applicants hereby elect to prosecute the invention of Group I, drawn to a peptide, in the present application. In addition, in response to the requirement for a species election, Applicants hereby elect

the species of original claim 5 covering SEQ ID NO: 6.

The election as between Groups I, II and III is made with traverse insofar as there is unity of invention of the claimed inventions under applicable PCT rules. In particular, there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features, namely peptides which are analogs of natural TGF β 1 or TGF β 1 receptor molecules that are present in a patient and which block the natural interaction between TGF β 1 and its receptor.

The Examiner has argued that the peptides recited in claim 1 cannot constitute a special technical feature as defined by PCT rule 13.2 because they allegedly do not define a contribution over the prior art as represented by WO 96/25178. Applicants respectfully disagree. WO 96/25178 describes **nucleic acids** encoding TGF β -specific inhibitory agents, and does not describe any of the claimed **peptides** which comprise an amino acid sequence that is sufficiently similar to a natural sequence so as to have antagonistic activity which prevents the natural TGF β 1-receptor interaction.

Even assuming *arguendo* that the cited art could be considered to prevent the peptides of claim 1 from being considered to constitute a special technical feature, the peptides presently recited in the Markush grouping of claim 17 constitute a special technical feature under applicable PCT rules. As discussed in Annex B of the Administrative Instructions Under the PCT, in the special situation of a Markush grouping, the requirement of a technical interrelationship and the same or

corresponding special technical features as defined in Rule 13.2 are met when the Markush alternatives are of a similar nature.

According to Annex B of the Administrative Instructions Under the PCT, a Markush grouping of alternatives of chemical compounds are of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property of activity, and

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

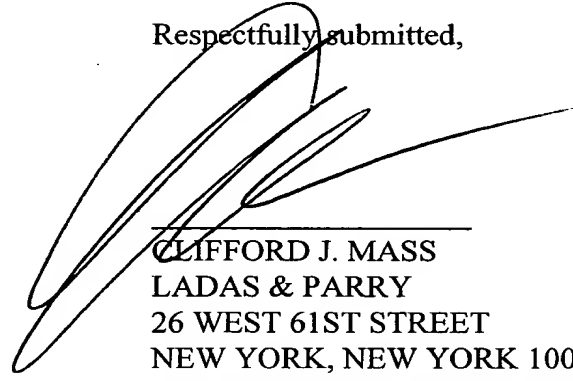
(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art not which the invention pertains.

In the present case, the peptides represented by SEQ ID NOs: 3-9 are all active in treating liver disease, specifically hepatic fibrosis, through the same physiological mechanism: antagonism of TGF β 1. All of these peptides thus pertain to the same recognized class of chemical compounds: TGF β 1 antagonists. Thus, the Markush grouping recited in claim 17 fulfills the requirements (A) and (B)(2) discussed above.

For the above reasons, it is respectfully submitted that all of the claims presently on file are in unity and that all claims should be examined in this application. In any event, claims 16, 17, 21 and 26-31 read on the elected invention and the elected species and should be examined in this application.

Applicants have now responded to all requirements in the Official Action and an early examination on the merits of at least the elected claims and species is respectfully requested.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'CLIFFORD J. MASS', is written over the typed name and extends to the right.

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